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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kevin D McCarthy
Roach Brown McCarthy & Gruber
1620 Liberty Building
Buffalo, NY 14202

EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,994	SEKLER ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 10 is objected to because of the following informalities: It contains a typographical error, "hypertention." Appropriate correction is required.

Claim Rejections - 35 USC § 101/112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 2, 3, 6, 7, and 9 require that the compound or composition be useful in treating or preventing cardiovascular diseases and related indications, particularly hypertension and stroke. Claims 8 and 10 are directed to methods of treating cardiovascular disorders by administering ZnT-1.

ZnT-1 is an integral membrane protein for transporting zinc across or through the cell membrane. (See at least prior art to Kim et al. (2000) and Palmiter et al.)

None of the examples in the specification administer ZnT-1 protein to any animal for any purpose. The examples either express the ZnT-1 protein in cells so that they function in the cell

membrane and can be tested or the examples test the properties of ZnT-1 in cells where this transporter naturally occurs in the cell membrane. It is not considered to be so predictable that if the isolated or purified protein were administered to a patient that any therapeutic effect would occur. It is unlikely that the protein would insert itself into any cell membrane (including vascular, heart, or brain cells) and have any effect as a modulator of LTCC function or intracellular calcium concentration. The prior art of record is silent as to administering the protein to a patient for any purpose.

Likewise, there is no explanation or evidence in the specification or of record as to why administration of ZnT-1 would have been expected to prevent any cardiovascular disease. A claim to prevention requires absolute non-occurrence of any "cardiovascular diseases or related indications." The specification provides no reason to believe that this would have been expected to occur for any or all of these conditions and no reason is apparent.

Finally, the specification discloses only the ZnT-1 of Palmiter et al., Genbank Accession No. U17132. (See pages 3, 8, and 9.) There is no structural definition for "ZnT-1" in the specification. To the degree that applicant intends the phrase "ZnT-1" to refer to other proteins, they are not described nor enabled. The ZnT-1 of Palmiter et al. is considered to be essential to the claimed invention; however, applicant has not clearly incorporated this sequence by reference. If applicant intended to incorporate this sequence by reference, the incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. See MPEP 608.01(p) and 37 CFR 1.57. Applicant is cautioned against introducing new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First of all, the specification fails to provide a structure or limiting definition of ZnT-1. It cannot be determined from the specification if Zn-T1 refers to a class of proteins or is limited to Genbank Accession No. U17132 (see page 9 of the specification). It is noted that this accession number is directed to a nucleotide sequence and not a protein sequence. It is further unclear if applicant is claiming a nucleic acid or a protein, although the context of the claims with respect to the required properties implies a protein.

Claim 1 is directed to Zn-T1. Claims 2-4 do not further limit this claim as there are no additional or different structural requirements to the ZnT-1 of claim 1.

Claims 2 and 6 recite "cardiovascular diseases and related indications." The claims and specification do not make clear what the metes and bounds of "related indications" are.

Claim 5 is directed to a composition comprising ZnT-1 and a optionally a pharmaceutically acceptable adjuvant, carrier, diluent or excipient. If the composition does not contain pharmaceutically acceptable adjuvant, carrier, diluent or excipient, then this claim would also fail to further limit the subject matter of claim 1. Claims 6-7 do not further limit the subject matter of claim 5 as there are no additional or different structural requirements for the composition of claim 5. Clarification is requested.

Claim 8 is confusing in reciting the "composition...optionally comprising." If this pharmaceutically acceptable adjuvant, carrier, diluent or excipient is not present, then the claim is administering ZnT-1 alone which has already been recited in the beginning of the claim. Clarification is requested.

Claim 9 provides for the use of ZnT-1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 8 and 10 are directed to methods of treating cardiovascular disorders, particularly hypertension or stroke. However, these claims do not make clear that the amount of ZnT-1 administered is sufficient to cause any particular effect and the particular effect required is not clear in the body of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Palmiter et al. (1995).

Palmiter et al. discloses the rat and mouse Zn-T1 zinc transporter protein. The protein was produced recombinantly and would have been in the presence of water (a pharmaceutically acceptable carrier).

The claims are directed to Zn-T1. Language such as "for use as" (claims 1 and 2), "for use in" (claim 3), "for blocking" (claim 5), and "for the treatment or prevention of" (claims 6-7) is considered functional language or intended use language and is given no patentable weight in a product claim. Because the specification asserts that Zn-T1 is the zinc transporter protein of Palmiter et al., any properties recited in the claims (see for example, claims 1 and 4) are considered inherent to this transporter as all of the structural requirements of the claims have been met.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marianne P. Allen
Primary Examiner
Art Unit 1647

6/14/07

mpa